CLAIMS

1. A composition comprising Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof and a stabilizing agent facilitating chemical and/or physical stability of LIF in the composition and one or more pharmaceutically acceptable carriers and/or diluents.

2. A composition according to claim 1 wherein the stabilizing agent facilitates reduced aggregation of LIF.

3. A composition according to claim 1 ~~or 2~~ wherein the stabilizing agent facilitates a reduction in the deamidation of LIF.

4. A composition according to claim 1 ~~or 2 or 3~~ wherein the pH of the composition is from between about 3.5 and 6.5.

5. A composition according to claim 3 wherein the pH of the composition is from between about 3.5 and 6.5.

6. A composition according to claim 1 ~~or 5~~ wherein the stabilizing agent is an isotonicity agent, an agent which increases or maintains the conformational stability of LIF or its derivatives or homologues or a surfactant or functional equivalents thereof.

7. A composition according to claim 6 wherein the stabilizing agent is an isotonicity agent selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

8. A composition according to claim 7 wherein the polyhydric alcohol is sorbitol.

9. A composition according to claim 6 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.

10. A composition according to claim 9 wherein the surfactant is selected from a fatty alcohol, a glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

11. A composition according to claim 6 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

12. A composition according to claim 7 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

13. A composition according to claim 12 wherein the buffer species is a citrate or acetate buffer.

14. A composition comprising Leukaemia Inhibitory Factor (LIF) and one or more pharmaceutically acceptable carriers and/or diluents and wherein the composition has a pH of between 3.5 and 6.5.

15. A composition according to claim 6 wherein the aggregation of LIF over time is reduced.

16. A composition according to claim 6 ~~or 7~~ wherein the deamidation of LIF over time is reduced.

17. A composition according to claim 14 where the pH is maintained by the presence of a buffer species selection from a phosphate, citrate and acetate buffer.

18. A composition according to claim 17 wherein the buffer species is a citrate or acetate buffer.

19. A composition according to claim 14, ~~17 or 18~~ wherein the pH is between from about 4.5 and about 5.5.

20. A composition according to claim 1 ~~or 14~~ wherein LIF is present in an amount from about 0.1 µg/ml to about 100 mg/ml.

21. A method for preparing a composition comprising Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof and which exhibits reduced deamidation and/or agglutination of LIF or its derivative or homologues over time said method comprising admixing LIF or its derivative or homologue with a stabilizing agent.

22. A method according to claim 21 wherein the stabilizing agent is a isotonicity agent, an agent which increases or maintains the conformational stability of LIF or its derivatives or homologues or a surfactant or functional equivalents thereof.

23. A method according to claim 22 wherein the stabilizing agent is an isotonicity agent selected form a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

24. A method according to claim 23 wherein the polyhydric alcohol is sorbitol.

25. A method according to claim 22 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.

26. A method according to claim 25 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

27. A method according to claim 22 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

28. A method according to claim 23 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

29. A method according to claim 28 wherein the buffer species is a citrate or acetate buffer.

30. A method according to ~~any of claims 22 to 29~~ Claim 21 further comprising adjusting the pH to between from about 3.5 and about 6.5.

31. A method according to claim 30 wherein the pH is between from about 4.5 and about 5.5.

32. A method according to ~~any one of the claims 22 to 31~~ Claim 21 further comprising admixing one or more pharmaceutically acceptable carriers and/or diluents.

33. Use of a stabilizing agent in the ~~manufacture~~ of a composition exhibiting improved chemical and/or ~~physical~~ stability of Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof.

34. Use according to claim 33 wherein the stabilizing agent is an isotonicity agent selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

35. Use according to claim 34 wherein the polyhydric alcohol is sorbitol.

36. Use according to claim 34 wherein the surfactant is an anionic, cationic, amphoteric

or non-ionic surfactant.

37. Use according to claim 36 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

38. Use according to claim 33 where the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative or a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

39. Use according to claim 34 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

40. Use according to claim 39 wherein the buffer species isa a citrate or acetate buffer.

41. Use according to ~~any one of claims 33 to 40~~ Claim 33 where the pH of the composition is between from about 3.5 to about 6.5.

42. Use according to ~~any one of claims 41~~ Claim 41 wherein the pH is between from about 4.5 and about 5.5.